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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,655	03/01/2006	Stefan Golz	004974.01084	4692

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BANNER & WITCOFF, LTD.
1100 13th STREET, N.W.
SUITE 1200
WASHINGTON, DC 20005-4051

EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
07/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,655	GOLZ ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *12-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/15/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignment*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-11) and the disease species "cancer" in the reply filed on 04/04/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicants' preliminary amendment filed upon 04/15/2005 has been entered in full. Claims 1-21 are pending. Claims 1-11 are under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Information Disclosure Statement

3. The information disclosure statement filed on 04/15/2005 is considered by the Examiner and a signed copy has been attached to the office action.

Claim Rejection —35 USC § 112, 1st paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 1-11 are drawn to a method of screening for therapeutic agents useful in the treatment of a disease, such as cancer, comprising determining binding of a test compound to a GPR14 polypeptide or determining the activity of a GPR14 polypeptide. There are no structural and functional limitations for the recited GPR14 polypeptide. A "GPR14 polypeptide" refers not only to a polypeptide having the sequence of SEQ ID NO: 2, but also a polypeptide which shows at least 80% homology with the polypeptide of SEQ ID NO: 2 (page 9 of the specification). Thus, the claims encompass a genus of a GPR14 polypeptide comprising SEQ ID NO: 2 and its variants and homologues.

The instant disclosure of a human GPR14 of SEQ ID NO: 2 does not provide adequate description for the genus of GPR14 polypeptides, which encompasses a substantial variety of homologues or variants of the human GPR 14 polypeptide of SEQ ID NO: 2. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence,

falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant disclosure fails to provide sufficient description information, such as definitive structural or functional features of the recited genus of GPR14 variants. There is no description of the conserved regions that are critical to the structure and function of the genus recited. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function.

The prior art teaches a human GPR 14 and a rat GPR14 (see, e.g., US Patent No. 6,159,700, Dec. 12, 2000). However, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed GPR14 polypeptide variants.

Accordingly, one skilled in the art would not recognize from the disclosure that the Applicants were in possession of the recited genus of GPR14 polypeptides and thus the claimed methods at the time the application was filed.

Claim Rejections—35 USC § 112, 2nd paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1-3 are indefinite because they recite the acronym "GPR14". Such a term is determined arbitrarily without a definitive structure. Others in the field may isolate the same protein and give an entirely different name. Thus, reciting biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly pointing out what the protein is. Applicants should particularly point out and distinctly recite characteristics associated with the protein, such as a sequence identifier.

Claims 2-3 recite "the activity of a GPR14 polypeptide". It is unclear what activity Applicants intend to determine. Since the specification does not define the term unambiguously, the claims are indefinite.

Claims 1-3 are indefinite because the steps of the methods do not necessarily achieve the goal set forth in the claim preamble. It is unclear how a therapeutic agent useful in the treatment of cancer is determined, selected, and correlated to the preamble. The Examiner notes that a method usually has a contacting step, a detecting step, a selecting step, and a correlation step linking the detection/selection step to the goal set forth in the preamble.

Claims 8-11 are rejected ass dependent claims from claim 1.

Claim Rejections—35 U.S.C. §102 (b)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-11 are rejected under 35 U.S.C. 102 (b) as being anticipated by Aiyar et al. (U. S. Patent No. 6,159,700, Dec. 12, 2000).

Aiyar et al. teach a human GPR14 polypeptide set forth in SEQ ID NO: 2, which is 100% identical the human GPR24 of SEQ ID NO: 2 of the present invention (See attached sequence alignment). Aiyar et al. teach a method for identifying a compound that binds to the human GPR24 the polypeptide, comprising contacting a cell expressing the human GPR24 polypeptide 2 with a candidate compound and detecting the ability of said candidate compound to bind to the polypeptide expressed in the cell (See, e.g., claims 1 and 2). Aiyar et al. teach a method for identifying an agonist or an antagonist of the human GPR24 polypeptide, comprising determining whether a test compound binds to and activates or inhibits said polypeptide activity by measuring the level of a signal generated from the interaction of the test compound with the human GPR14 polypeptide (see claim 3) and determining the activity of human GPR14 polypeptide in the presence of human urotensin II (See e.g., claim 4).

Aiyar et al. also teach a competitive binding assay, comprising determining the inhibition of binding of a known ligand to cells which have said polypeptide on the

surface thereof in the presence of a candidate compound and determining the amount of ligand bound to the human GPR14 polypeptide (See, e.g., claims 5 and 6; column 17, the 6th paragraph). Aiyar et al. further teach cell-free assay system (column 16, lines 58-62), use of a radiolabeled ligand in a ligand binding assay (See, e.g., Example 4), and use of a labeled GPR14 polypeptide, such as a fusion protein, in an assay system (page 20, lines 19 to page 21, line 12). Since a screening assay based upon a cell-free assay system has to be carried out in a container, such as a multiwell plate, some of the human GPR14 polypeptide or a test compound/ligand would necessarily be bound to the container, i.e., a solid support.

Accordingly, the teachings of Aiyar et al. meet the limitations of claims 1-11.

Claim Objections—Minor Informality

10. Claim 1-3 are objected to because they recite non-elected species. Appropriate correction is required.

Conclusion

11. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00

pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
July 8, 2008